UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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IN RE INTERCEPT PHARMACEUTICALS, INC. SECURITIES LITIGATION

MEMORANDUM AND ORDER

14 Civ. 1123 (NRB)

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NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE

These actions are brought pursuant to §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 against Intercept Pharmaceuticals, Inc. ("Intercept") and its Chief Executive Officer and Chief Medical Officer, on behalf of a purported class of investors who purchased securities of Intercept between January 9 and 10, 2014 (the "Class Period"). Defendants have moved to dismiss the Consolidated Amended Complaint ("CAC") pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4. For the reasons stated herein, this motion is denied.

BACKGROUND

I. Factual Background

Intercept is a biopharmaceutical company founded in 2002 that became publicly traded in October 2012. Id. ¶ 16. In the years leading up to the class period, Intercept was working to develop and market obeticholic acid ("OCA") as a treatment for various

liver ailments, including nonalcoholic steatohepatitis ("NASH"), a disease whereby a fat build-up in the liver causes chronic inflammation leading to progressive fibrosis, cirrhosis, and possibly liver failure. Id. ¶¶ 3, 23, 26. While approximately twelve percent of the general population of the United States is affected by NASH, there are currently no drugs approved for its treatment, making development of an approved treatment option a lucrative endeavor. Id. ¶ 27.

A trial for OCA as treatment for NASH, known as the "FLINT" trial, was conducted by the National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK"), an agency at NIH. Id. ¶¶ 4, 28-29. Accomplished pursuant to a cooperative research and development agreement entered into by NIDDK and Intercept in July 2010, FLINT was run by NIDDK and was funded primarily by the agency. Id. ¶ 28. FLINT tested a 25 mg daily dose of OCA versus placebo in 280 patients with NASH over a 72-week treatment phase, to be followed by a 24-week post-treatment follow-up phase. Id. ¶ 30; Def's Br. at 4-5. The results of the trial were determined primarily by periodic liver biopsies, and the primary endpoint in FLINT was defined as an improvement of two or more points in the nonalcoholic fatty liver disease ("NAFLD") activity score (a system of scoring the histopathological features in the liver) with no worsening of liver fibrosis or other safety issues. CAC ¶ 30.

On January 6, 2014, Intercept's Chief Medical Officer, Dr. David Shapiro ("Shapiro"), had a telephone call with NIDDK's Scientific Advisor for Viral Hepatitis and Liver Diseases, Dr. Averell Sherker ("Sherker"). CAC ¶ 33. According to Sherker's official record of the conversation, Sherker informed Shapiro that the FLINT trial was being stopped early. Id. ¶ 34. Specifically, Sherker reported that "upon planned interim analysis, the stopping boundary for efficacy was crossed and NIDDK has decided not to have subjects undergo week 72 biopsies effective today." Id. He noted that "Dr. Shapiro was informed that given this decision and the finding of significant lipid abnormalities (increased total cholesterol, increased LDL cholesterol and decreased HDL cholesterol), all patient[s] who remain on treatment (OBCA or Placebo) will be discontinued within two weeks of today." Id. He also recorded that "Dr. Shapiro mentioned that he was aware of SAEs as Intercept has been copied on all reports submitted to FDA," and that "Intercept has a previously scheduled Quarterly Webinar on January 9 and will mention that NIDDK has informed them that the treatment phase of the study has been terminated on the basis of efficacy and that lipid abnormalities have been observed. Additionally, Intercept will release a press release with the same information. As a courtesy, they will send me the press release for review prior to issuing it." Id.

On January 7, 2014, Shapiro emailed Sherker regarding Intercept's planned January 9 disclosure. Id. ¶ 35. In the email, Shapiro informed Sherker that, after conferring with Intercept's CEO, Mark Pruzanski ("Pruzanski"), Intercept intended to issue a press release stating that the study was being stopped after having met the efficacy endpoint and that "[f]urther details will be available when the study is presented at a scientific meeting and/or published . . . ."[1] Id. He also told Sherker that "[w]e don't think that without the specific data, we can comment on the lipid changes. We have previously reported HDL and LDL changes (see attached)." Id. Finally, he asked Sherker to get in touch with "any thoughts/disagreements . . . ASAP." Id.

Sherker responded with an email later that day. He wrote, in pertinent part, "[w]ith respect to the lipid abnormalities, I will defer to you about the decision whether or not to include it in your press release. As I mentioned yesterday, the NIDDK decision to terminate therapy was primarily due to the efficacy effect but,

[1] Shapiro's email stated in part: "Following our call, I spoke with Mark Pruzanski, our CEO and we plan to draft a simple press release today that I'll forward to you prior to our release (although SEC regulations bind us to issuing a public statement to within 72 hours). I think that we should just aim to keep the release simple and note the key points being: NIDDK have informed Intercept that a planned interim efficacy analysis was conducted which showed that OCA produced a highly significant improvement on the protocol specified liver histology endpoint, compared with placebo. The improvement met (p=0.0015) the protocol criterion for stopping the study and accordingly NIDDK have informed Intercept that they are stopping the study. Further details will be available when the study is presented at a scientific meeting and/or published and Intercept looks forward to seeing the full results from the study." Id.

in part, influenced by the significant lipid abnormalities observed in the OCA-treated subjects." Id. ¶ 36.

On January 9, 2014, as planned, defendants filed a form 8-K and issued a press release entitled "Intercept Announces NASH Primary Endpoint Met: FLINT Trial Stopped Early for Efficacy Based on Highly Statistically Significant Improvement in Liver Histology." Id. ¶ 37. The release reported that "the FLINT trial of obeticholic acid (OCA) for the treatment of nonalcoholic steatohepatitis (NASH) has been stopped early for efficacy based on a planned interim analysis showing that the primary endpoint of the trial has been met." Id. It made no mention of any lipid abnormalities or effects. Following this release, OCA received vast media coverage and Intercept's stock price rose from $72.39 to $275.87 per share. Id. ¶¶ 39-40.

After the close of trading on January 9, 2014, defendants held a conference call with analysts and investors, at which both Pruzanski and Shapiro participated. Id. ¶ 41. There, Pruzanski announced that NIDDK "recommended stop of the trial early for efficacy. This was based on an interim analysis showing that OCA had met the primary histological endpoint. The decision to stop early was based on a predefined requirement that OCA show a much great efficacy benefit with better than AP value of .0031 on an intention-to-treat basis." Id. He added that "[a]t this point, NIDDK has only shared the statistical result of the interim

efficacy analysis with us, so we don't have additional data to share with you today. . . . Of course, when we get the data in hand from NIDDK, we will share the results with you." Id. ¶ 42. The next day, January 10, 2014, following the press release and the conference call, Intercept stock reached an intraday high of $497 per share, ultimately closing at $445.83 per share. Id. ¶ 44.

Later on January 10, Sherker sent Shapiro an email alerting him that "NIDDK and the NASH CRN investigators have had a number of media requests for additional information related to FLINT. We have developed the attached statement as a standardized response to specific media inquiries. However, because the results are preliminary and the trial is ongoing, we are not granting interviews." Id. ¶ 46. The attached NIDDK document included a statement that mirrored Sherker's January 6, 2014 notes, stating that "FLINT interim results also found disproportionate lipid abnormalities (increased total cholesterol with increased LDL and decreased HDL cholesterol) in patients on OCA compound to those on placebo." Id. ¶ 47.

Shapiro first responded briefly to Sherker's email, stating that "I'm about to leave JFK to go home, I suggest we speak on Monday. I had no idea the press release would have the impact it did--it's rather scary!" Id. ¶ 48. Three minutes later, apparently following a communication with Pruzanski, Shapiro sent

another email to Sherker, asserting that "[t]he lipid information is specific and I think will cause issues. If this hasn't been issued can we discuss first. At least it would be good to mention that similar findings had been seen previously." Id. ¶ 49.

NIDDK proceeded to release its statement later on January 10, 2014. Id. ¶ 50. As Sherker had indicated, the release stated that "FLINT interim results also found disproportionate lipid abnormalities (increased total cholesterol with increased LDL and decreased HDL cholesterol) in patients on OCA compared to those on placebo. As lipid abnormalities are common in people with NASH, following all FLINT patients the full 24 weeks after stopping the drug will help determine whether lipid problems return to pre-OCA levels and weigh potential risks and benefits of the drug." Id. It also noted that "NIDDK does not typically release interim results as they are preliminary. But as results have already been made public, we are providing limited additional information, giving a broader context for the findings." Id.

Media coverage seized upon NIDDK's statement and the news of the lipid abnormalities. Id. ¶¶ 51-52. In response, on January 12, 2014, Intercept issued a press release and filed an 8-K confirming NIDDK's statement. Id. ¶ 53. On Monday, January 13, 2014, Intercept's stock price dropped to $190.71 per share. Id. ¶ 54.

II. Procedural Background

Plaintiffs filed these class actions on February 21 and February 24, 2014, respectively. On May 16, 2014, we consolidated the actions as "In re Intercept Pharmaceuticals, Inc. Securities Litigation," appointed George Burton as lead plaintiff, and approved his selection of lead counsel.

On June 27, 2014, plaintiffs filed the Consolidated Amended Complaint, alleging violations of Sections 10(b) and 20(a) of the Exchange Act and of Rule 10b-5. In particular, plaintiffs allege violations of the securities laws based on Intercept's omission of "the significant lipid abnormalities identified in the FLINT trial or the fact that these safety issues contributed to the NIDDK's decision to stop the FLINT trial." CAC ¶¶ 38, 45.

On August 14, 2014, defendants filed the present motion to dismiss, challenging the CAC for failure to adequately plead scienter.[2] The motion was fully briefed on October 13, 2014, and oral argument was held on February 24, 2015.

[2] Intercept challenges the CAC solely on scienter grounds and, "for purposes of this motion only, Intercept does not . . . contest materiality." Def's Reply at 6. Accordingly, we address only the issue of scienter.

DISCUSSION

I. Legal Standards

A. Motion to Dismiss

On a motion to dismiss under Rule 12(b)(6), the Court must accept as true all factual allegations in the complaint and draw all reasonable inferences in plaintiff's favor. ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir. 2007) ("ATSI"); Grandon v. Merrill Lynch & Co., 147 F.3d 184, 188 (2d Cir. 1998). Nonetheless, "[f]actual allegations must be enough to raise a right of relief above the speculative level, on the assumption that all of the allegations in the complaint are true." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007); see also Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Thus, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." If a plaintiff "ha[s] not nudged [his] claims across the line from conceivable to plausible, [his] complaint must be dismissed." Id. This pleading standard applies in "all civil actions." Iqbal, 556 U.S. at 684 (internal quotation marks omitted).

B. Securities Fraud

In order to sustain a private cause of action for securities fraud under Section 10(b) and Rule 10b–5 of the Securities Exchange Act of 1934 (the "Exchange Act"), a plaintiff must adequately plead: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the

misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." Ashland Inc. v. Morgan Stanley & Co., 652 F.3d 333, 337 (2d Cir. 2011) (quoting Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc., 552 U.S. 148, 157 (2008)). In addition, claims brought under Section 10(b) and Rule 10b–5 are "subject to heightened pleading requirements that the plaintiff must meet to survive a motion to dismiss." ATSI, 493 F.3d at 99. These heightened pleading requirements are set forth in Rule 9(b) of the Federal Rules of Civil Procedure and in the PSLRA, 15 U.S.C. § 78u–4(b). ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co. ("ECA"), 553 F.3d 187, 196 (2d Cir. 2009).

In order to satisfy Rule 9(b), a plaintiff must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." Rombach v. Chang, 355 F.3d 164, 170 (2d Cir. 2004) (internal quotation marks omitted). "Allegations that are conclusory or unsupported by factual assertions are insufficient" to prevail under this standard. ATSI, 493 F.3d at 99.

The PSLRA has expanded on Rule 9(b)'s pleading requirements. See 15 U.S.C. § 78u–4(b). "The statute insists that securities fraud complaints 'specify' each misleading statement; that they

set forth the facts 'on which [a] belief' that a statement is misleading was 'formed'; and that they 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 345 (2005) (quoting 15 U.S.C. §§ 78u–4(b)(1), (2)). "Therefore, 'while we normally draw reasonable inferences in the non-movant's favor on a motion to dismiss,' the PSLRA 'establishes a more stringent rule for inferences involving scienter' because the PSLRA requires particular allegations giving rise to a strong inference of scienter." ECA, 553 F.3d at 196 (2d Cir. 2009) (internal alteration omitted) (quoting Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc., 531 F.3d 190, 194 (2d Cir. 2008)).

C. Scienter

Under the PSLRA, it is necessary to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," 15 U.S.C. § 78u-4(b)(2), namely an "intent 'to deceive, manipulate, or defraud.'" ECA, 553 F.3d at 198. In assessing whether a plaintiff has met its burden of pleading a strong inference of scienter, a court must "take into account plausible opposing inferences," and the "complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing

inference one could draw from the facts alleged." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 324 (2007).

A strong inference of scienter may be established by alleging facts demonstrating either (a) "that defendants had both motive and opportunity to commit fraud," or (b) "strong circumstantial evidence of conscious misbehavior or recklessness." Kalnit v. Eichler, 264 F.3d 131, 138 (2d Cir. 2001).

To raise a strong inference of scienter through the motive and opportunity prong, a plaintiff must allege that the defendant "benefitted in some concrete and personal way from the purported fraud." ECA, 553 F.3d at 198. "Motives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from the fraud. Insufficient motives, we have held, can include (1) the desire for the corporation to appear profitable and (2) the desire to keep stock prices high to increase officer compensation. On the other hand, we have held motive sufficiently pleaded where plaintiff alleged that defendants misrepresented corporate performance to inflate stock prices while they sold their own shares." Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001) (citing Novak v. Kasaks, 216 F.3d 300, 307-308 (2d Cir. 2000)).

"Where motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating conscious

behavior by the defendant;" however, "the strength of the circumstantial allegations must be correspondingly greater." Kalnit, 264 F.3d at 142. "To survive dismissal under the 'conscious misbehavior' theory, the [plaintiffs] must show that they alleged reckless conduct by the [defendants], which is 'at the least, conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.'" Id. (quoting Honeyman v. Hoyt (In Re Carter-Wallace, Inc. Secs. Litig.), 220 F.3d 36, 39 (2d Cir. 2000)). See also In re Citigroup Inc. Sec. Litig., 753 F. Supp. 2d 206, 236 (S.D.N.Y. 2010) ("Plaintiffs can sustain a claim of securities fraud if they can plead particularized facts giving rise to a strong inference that one or more of defendants was at least reckless in misleading investors . . . .").

II. Analysis

A. Motive and Opportunity

Defendants argue that plaintiffs have failed to allege scienter based on motive and opportunity "given that there are no allegations of insider sales or secondary offerings or financings during the brief putative class period." Def's Br. at 13. Plaintiffs counter that scienter can be inferred from the fact that Intercept was "quickly running through the funds raised in

earlier stock offerings" for its ongoing expenses for research and development, Pl's Opp'n at 23, and they posit that Intercept sought to inflate its stock price in advance of a contemplated secondary offering that would ultimately take place in April 2014. See id. at 23-24 ("With a critical stock offering being planned, Defendants disclosed the positive news about OCA and the FLINT trial and assumed that the concurrent negative news would not be disclosed before they had the opportunity to complete the offering.").

We agree with defendants that these allegations, essentially accusing defendants of withholding information to keep stock prices high in service of furthering the company's profitability, are too generalized to support a strong inference of scienter. See, e.g., In re Bayer AG Sec. Litig., 03 Civ. 1546 (WHP), 2004 WL 2190357, at *14 (S.D.N.Y. Sept. 30, 2004) (rejecting motive-and-opportunity scienter claim based on allegations that "Ebsworth had the motive to engage in fraud because the Company was under pressure to bring a 'blockbuster' drug to market and thus . . . had an incentive to turn a blind eye to safety considerations," because "to allege motive in the securities context, plaintiffs must show that a defendant possessed a concrete incentive for personal gain--not simply the desire to increase a company's profitability--a goal shared by any corporate officer"); Johnson v. NYFIX, Inc., 399 F. Supp. 2d 105, 114 (D. Conn. 2005) ("Plaintiffs further allege that defendants used artificially

inflated NYFIX stock to raise funds in a secondary offering, and then purchase partial or full interest in four other companies during the Class Period. Courts have previously held this claim insufficient to establish motive [and t]he plaintiffs 'do not expressly or even inferentially explain how the desire to conclude various acquisitions by using inflated value of the stock as consideration for mergers and to obtain financing for such acquisitions is in the informed economic self-interest of the Individual Defendants beyond those expressly rejected by the Court [in previous cases].'") (internal citations omitted) (quoting Rombach v. Chang, 355 F.3d 164, 177 (2d Cir. 2004)).

Further, the timing of the secondary offering--"planned" in January 2014 and not completed until four months later--does not expose a clear motive to commit fraud; rather, the allegation that Intercept would deliberately choose not to discuss lipid abnormalities in the hope of inflating a secondary offering several months away is too attenuated to create the requisite strong inference of scienter, particularly given that Intercept promised to release full findings from NIDDK as soon as they were available. See, e.g., In re Axis Capital Holdings Ltd. Sec. Litig., 456 F. Supp. 2d 576, 596 (S.D.N.Y. 2006) ("Here, the timing of the Secondary Offering raises no inference of fraud. . . . There is no 'suspicious' or 'unusual' relationship between the timing of the Secondary Offering and any allegedly false statements or negative

revelations. In short, the timing of the Secondary Offering was at best fortuitous, and simply does not appear calculated to maximize personal benefit from insider information.") (internal quotation marks omitted).

B. Conscious Misbehavior or Recklessness

Next, defendants argue that plaintiffs have failed to plead that Intercept was reckless or "consciously misbehaving" in failing to disclose the lipid information received by Sherker. Asserting that "Intercept had no intent to deceive, but made a reasonable and good faith determination, with the consent of the trial's government sponsor, not to discuss lipid abnormalities with the public until it had actual data," defendants maintain that the nondisclosure was the result of an honest belief in the irrelevance, scientific insignificance, and/or commercial insignificance of the reported lipid finding. Def's Br. at 15-16. In addition, they argue that an inference of scienter is undermined by their demonstrated belief that the lipid consequences of OCA were already known to the public and their generally cautious and conscientious approach to reporting the news that FLINT had met its efficacy endpoint. Id. at 19-21.

Where pharmaceutical companies release information that is found to be more positive than warranted, critical questions to be asked are whether at its issuance "the management honestly believes [these reports] to be true" and/or whether the reports evince

"reckless disregard for truth." In re AstraZeneca Sec. Litig., 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008) aff'd sub nom. State Universities Ret. Sys. of Illinois v. Astrazeneca PLC, 334 F. App'x 404 (2d Cir. 2009). "[I]f the management knows that certain facts will necessarily prevent the regulatory approval or the marketing of the drug and conceals these facts from the investing public, then there is scienter. There is also scienter if the management is reckless in dealing with such adverse facts." Id.

We find that Intercept's failure to include any mention of the lipid findings reported by Sherker gives rise to a sufficient inference of scienter at this stage of litigation. In essence, Intercept was informed by Sherker that treatment would be stopped on the basis of a positive development ("[G]iven this decision [that 'the stopping boundary for efficacy was crossed'] . . . treatment will be discontinued") and on the basis of a negative development ("[G]iven . . . the finding of significant lipid abnormalities . . . treatment will be discontinued"). Intercept chose, however, only to report the positive development, engaging in the sort of selective disclosure that creates a real possibility of misleading investors.

More tellingly, Intercept did not simply issue its release upon speaking to Sherker, but it sought subsequent approval from Sherker on the decision to report the positive (endpoint news) while excluding the negative (lipid finding). Rather than receive

approval for the selective disclosure, however, Intercept was told that Sherker "defer[red]" to its decision and, further, was explicitly reminded that the negative development played a part in the decision to stop the study being reported. While it is true that Intercept was not bound by Sherker's conclusions regarding what disclosures were necessary to accurately and fully report the trial news, the fact that Intercept sought out Sherker's opinion on the issue only to largely disregard his response suggests that its decision not to disclose the lipid finding constituted knowing conduct: in other words, it appears that Intercept did not merely overlook the role played by the lipids, but specifically considered whether the company could avoid reporting the finding and, in the absence of a clear yes or no from Sherker, decided not to disclose the negative information.

The final set of emails between Shapiro and Sherker also supports plaintiffs' claims that Intercept acted consciously and recklessly in failing to disclose the lipid finding. Specifically, Shapiro's stated concern that the lipid information in the statement--which mirrors exactly what Sherker originally disclosed to Shapiro--"will cause issues" and thus should not be announced by NIDDK suggests that Intercept may have itself chosen not to report the findings not because they were insignificant or uncertain but because they would "cause issues." Additionally, in the same email, Shapiro notes that this information is "specific."

Taken together, these allegations are sufficient to give rise to a compelling inference of conscious-misbehavior scienter at this stage.

Defendants argue that, rather than an inference of conscious misbehavior, Shapiro's correspondence with Sherker evinces a stronger inference that Intercept "reasonably believed that the omitted information was irrelevant or not scientifically or commercially significant" and therefore did not act with scienter. Def's Br. at 15-16. In particular, they note that Sherker failed to provide Intercept with "actual data to indicate that the lipid abnormalities had any material scientific significance" and assert that Sherker's "consent" to the nondisclosure (i.e. his failure to indicate that he thought the lipid nondisclosure was misleading) supported Intercept's good-faith belief that the lipid finding was irrelevant or insignificant. Id. at 23.

However, based on the current record, we find it difficult to concur with defendants' suggestion that the record supports a sufficient inference that Intercept honestly and reasonably believed that the lipid data was "irrelevant" or "scientifically insignificant." For one, Sherker's email--in which he sounded a cautionary note about the reasons for the early study endpoint and "defer[red]" to Intercept's decision on disclosure--cannot be said to constitute meaningful or affirmative "consent" to the press release, such that defendants would have reasonably believed that

he supported or validated the nondisclosure. Rather, Sherker's emails declared that the lipid finding was an "influen[tial]" factor in the decision to end the study, and they repeatedly used the term "significant" to describe the lipid abnormalities. A belief that these abnormalities were irrelevant or insignificant would thus seem to arise in spite of, rather than as a result of, the information provided by NIDDK. Cf. In re Delcath Sys., Inc. Sec. Litig., 13 Civ. 3116 LGS, 2014 WL 2933151, at *12 (S.D.N.Y. June 27, 2014) (rejecting defendants' claim that there is no scienter where "management honestly believes its positive view of the data from its trials, even though the FDA may have had a different interpretation," and noting that "[w]hile the FDA's disagreement with management's interpretation of data does not create a misstatement on the part of management, the disagreement may help support a strong inference of scienter"). In addition, as noted earlier, defendants' claims that they believed the lipid data was irrelevant or as-yet scientifically insignificant would seem to be belied by Shapiro's characterization of NIDDK's parallel disclosure in his January 10 email as "specific" and likely to "cause issues."

Defendants seek to support their position with cases in which pharmaceutical companies are given raw data that, when later analyzed, revealed adverse conclusions. That fact pattern, however, is meaningfully distinguishable from--and, indeed,

perhaps the converse of--the one at issue here. In such cases, pharmaceutical companies do not meet the scienter requirement because they did not realize the statistical significance of their own raw data at the time they made (or failed to make) a statement, and courts have affirmed that companies may take some time to reach conclusions from raw data. See, e.g., State Universities Ret. Sys. of Illinois v. Astrazeneca PLC, 334 F. App'x 404, 407 (2d Cir. 2009) ("Drug companies need not disclose isolated reports of illnesses suffered by users of their drugs until those reports provide statistically significant evidence that the ill effects may be caused by--rather than randomly associated with--use of the drugs and are sufficiently serious and frequent to affect future earnings."); Koncelik v. Savient Pharm., Inc., 08 Civ. 10262 (GBD), 2010 WL 3910307, at *7 (S.D.N.Y. Sept. 29, 2010) aff'd, 448 F. App'x 154 (2d Cir. 2012) (rejecting the claim that defendants were "consciously misbehaving or reckless, in publicly disclosing the first three cardiovascular SAEs without disclosing the remaining five cardiovascular SAEs, because they knew or should have known that this established a statistically significant link between the drug and the cardiovascular SAEs."); In re Sanofi-Aventis Sec. Litig., 07 Civ. 10279 (GBD), 2009 WL 3094957, at *7 (S.D.N.Y. Sept. 25, 2009) (rejecting scienter claim based on defendants' failure to realize safety details of drug "given their access to clinical study data"). Here, by contrast, Intercept did not have raw data,

but it did have NIDDK's statement that the lipid finding was "significant," and apparently significant enough to have influenced the decision to terminate the therapy. Moreover, given that only NIDDK and not Intercept was in the position of collecting and assessing trial data, such that Intercept was generally positioned to merely report NIDDK's findings rather than make its own, the contention that Intercept needed to wait for further data or assessment in this instance rather than relay NIDDK's finding is unpersuasive.

Defendants' related argument that they reasonably believed the lipid finding would not have commercial significance, and therefore did not act with scienter in failing to disclose it, is also unavailing. While some courts do place an emphasis on whether companies understood that the information threatened the commercial viability of the product or company in evaluating whether the nondisclosure was made with scienter, see, e.g., In re AstraZeneca Sec. Litig., 559 F. Supp. 2d 453, 471 (S.D.N.Y. 2008) aff'd sub nom. State Universities Ret. Sys. of Illinois v. Astrazeneca PLC, 334 F. App'x 404 (2d Cir. 2009) ("Nothing appears in the complaint showing that there was a consensus of the management that the risks of Exanta made the drug unlikely to be approved"), such an evaluation of commercial viability need not be determinative. See, e.g., In re Citigroup Inc. Sec. Litig., 753 F. Supp. 2d 206, 238 (S.D.N.Y. 2010) ("Defendants contend that

none of Citigroup's actions suggest 'any knowledge on Citigroup's part that losses would be suffered.' This argument erroneously presupposes that plaintiffs must show that defendants were clairvoyant. Defendants could have been reckless in failing to disclose this information even absent knowledge that the CDO holdings would certainly suffer losses."); City of Livonia Employees' Ret. Sys. v. Wyeth, 07 Civ. 10329 (RJS), 2010 WL 3910265, at *6-7 (S.D.N.Y. Sept. 29, 2010) (finding scienter where defendants allegedly failed to disclose statistically significant adverse information from study of drug that was of "critical importance" to company, because they "should have been aware of the impact of Study 315's results on Wyeth's stock [when] they recklessly omitted the information") (emphasis added). Here, while it is possible that the lipid finding would prove to be a surmountable obstacle in the drug's development and that defendants have honestly believed this to be the case, Sherker's emails make clear that the lipid finding is a meaningful concern that could cause problems for the drug's approval and commercial success, and thus about which defendants should have been cautious.

We also reject defendants' argument that they acted without scienter because they "believed that the fact that lipid abnormalities had already been observed in patients taking OCA was already known to the public." Def's Br. at 19. Specifically, defendants claim that "the results of a prior trial--including

lipid changes like those generally described by NIDDK--had been disclosed in a prominent medical journal in 2013 and had at all times since its IPO been part of Intercept's public filings," and that these disclosures negate scienter either because information simply cannot be actionably withheld when it is already known to the public, see, e.g., In re GeoPharma, Inc. Sec. Litig., 411 F. Supp. 2d 434, 448 (S.D.N.Y. 2006), or at least because the parties reasonably believed that the information was already public and therefore did not seek to withhold it in bad faith. However, the previously reported findings cannot be so easily conflated with the findings of the NIDDK trial. As plaintiffs point out, the prior results derived from "a six week 'exploratory study' (not a 72-week 'multi-center, double-blinded, placebo controlled' like the FLINT trial), conducted by Intercept (not the NIDDK)," for patients with NAFLD (a precursor to NASH) who also had type 2 diabetes. Pl's Opp'n at 21-22; Def's Reply at 9 n. 9. The two studies are thus meaningfully different, such that the existence of lipid abnormalities in the later study cannot be inferred or expected from the existence of lipid abnormalities in the former study and therefore reasonably known to investors. Cf. Kalnit v. Eichler, 264 F.3d 131, (2d Cir. 2001) (no scienter where defendants who had announced a merger agreement failed to disclose letter suggesting company might receive and act on a superior proposal, given that the terms of the merger agreement gave defendants 45

days to accept a superior proposal, making acceptance of superior proposal reasonably inferred or expected from the terms of the merger agreement). Such differences undermine both defendants' contention that the information was in fact already public and the reasonableness of their belief that disclosure was unnecessary.

Finally, we reject defendants' claims that their conduct manifested such cautiousness or conscientiousness as to defeat an inference of scienter. For instance, defendants assert that they were not reckless because they were "careful to caution investors." Def's Br. at 21. However, in support, defendants point solely to one comment made by Pruzanski in the January 9 conference call that he did not "want to overplay where we are," id., which, as plaintiffs note, was in fact directed to the number of patients diagnosed with NASH rather than the efficacy finding or trial results. Defendants' attempt to characterize the statement as more broadly "indicative of [their] general mindset of tempering optimism with caution" overstates Intercept's level of care, especially when Intercept's statements are compared to other cases in which defendants, found not to have scienter, have meaningfully cautioned investors about their findings. See, e.g., In re AstraZeneca Sec. Litig., 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008) aff'd sub nom. State Universities Ret. Sys. of Illinois v. Astrazeneca PLC, 334 F. App'x 404 (2d Cir. 2009) (no scienter where "the information provided by defendants made clear that certain

side effects were being manifested in the testing, particularly regarding the risk of liver injury" and "public communications continually noted that there would need to be an ultimate risk-benefit evaluation, and that it was uncertain what this evaluation would show").

In sum, plaintiffs' allegations are sufficient at this stage of litigation to suggest that Intercept consciously chose not to disclose the lipid information, which it knew or should have known to be a significant negative finding, and that it therefore acted with scienter. See City of Livonia Employees' Ret. Sys. v. Wyeth, 07 Civ. 10329 RJS, 2010 WL 3910265, at *6-7 (S.D.N.Y. Sept. 29, 2010) ("Plaintiffs have alleged that not all of the information from [the study] was revealed to the public during the Class Period and that the study provided statistically significant evidence to Defendants that serious adverse events may have been caused by the use of [the drug]. As discussed supra, Plaintiffs allege [the drug] had 'critical importance' to [the company]. . . . Therefore, at least at this stage of the litigation, Plaintiffs have made sufficient allegations that Defendants should have been aware of the impact of [the study's] results on [the company's] stock and that they recklessly omitted the information when making their

statements during the Class Period. Accordingly, Plaintiffs have adequately alleged scienter.").[3]

CONCLUSION

For the aforementioned reasons, defendants' motion to dismiss is denied. This Memorandum and Order resolves Docket No. 29. Finally, the parties should confer and submit a proposed schedule for further proceedings.

SO ORDERED.

Dated: New York, New York
March 4, 2015

NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE

[3] Because we reject defendants' challenge to plaintiffs' allegations under § 10(b) and Rule 10b-5, we also reject defendants' contention that plaintiffs' §20(a) control liability claims fail because plaintiffs have not pled a primary violation of the securities laws.

Copies of the foregoing Memorandum & Order have been mailed on this date to the following:

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